Manufactured by OraSure Technologies, Inc.

OraQuick® Rapid HIV-1

OraQuick® is the only FDA approved, CLIA-waived, point-of-care test, which can be used in the diagnosis of HIV-1 infection. The test, which detects the presence of antibodies to HIV-1, requires only a drop of blood and can produce results in 20 minutes.

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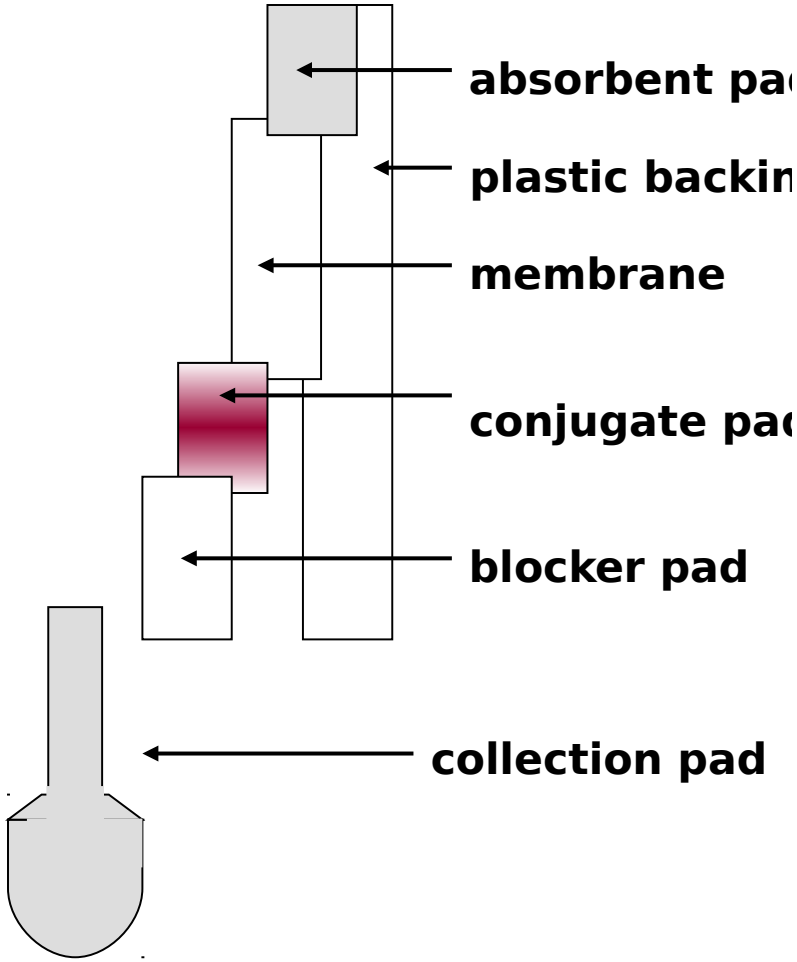
OraQuick® Rapid HIV-1 Test

- Single-use testing device
- Single-use test developer solution vial
- Reusable Test Stand
- Disposable single-use specimen collection loop

OraSure Technologies, Inc.

The collection device



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General Test Preparation

Place the test stand on a flat surface. Use only the stand provided.

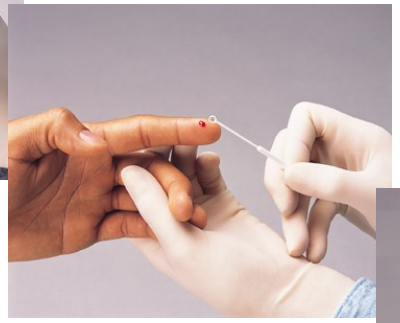
Remove the vial of developer solution.

Firmly holding the vial, carefully uncap the vial by gently rocking the cap back and forth.

Slide the now uncapped vial into the angled stand making sure the vial is completely seated in the stand.

DO NOT snap the vial into the stand as splashing may occur.

Fingerstick Blood Test



Clean finger with an antiseptic wipe. Use a lancet to puncture finger.

Touch the specimen collection loop to the blood.

Put the blood-filled loop into the developer solution inside the vial. Use the loop to stir the specimen in the vial of developer solution.

Fingerstick Blood Test (cont.)

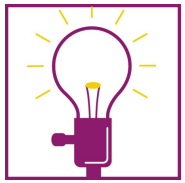
Insert the testing device, flat pad first, into the test developer solution vial containing the specimen.

Start timing the test. Read the results after 20 minutes.

Reading Test Results

Reading an ***Invalid*** result:

- No line appears in the control (C) area, indicating that the test did not function properly (examples a & b).
- If line is outside of the blue triangle the test is invalid. (example c)



Appropriate Lighting Required

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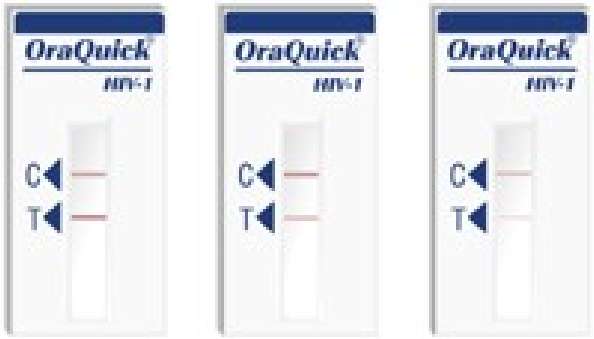
Reading Test Results (cont.)

Reading a ***Negative*** result:

- Only the control (C) area shows a line.
- No line is present in the test (T) area.
- A negative test suggests an absence of HIV antibodies in the specimen.



Reading a ***Reactive*** result:

- Lines appear in both the control (C) and test (T) areas. Even a very faint test (T) band should be read as reactive.
- One line may appear lighter or less consistent than the other.
- A reactive result indicates the presence of HIV antibodies in the specimen.

Screening in the DOD

- *Readiness*
  - Contraindication with live virus vaccinations
  - Contraindication to give multiple immunization
- *Deployment*
  - Potential exposure to exotic diseases
  - Limited access to sophisticated care in field settings
  - Field transfusion of unscreened blood
- *Health of the Individual*
  - Early diagnosis and early treatment
- *Public Health*
  - Decrease “unwitting” transmissions

Contact Information

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